

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

IN RE NEW ENGLAND COMPOUNDING  
PHARMACY, INC. PRODUCTS LIABILITY  
LITIGATION

THIS DOCUMENT RELATES TO:

## All Cases

MDL No. 2419  
Dkt. No 1:13-md-2419 (RWZ)

**MEMORANDUM IN SUPPORT OF SAINT THOMAS ENTITIES’  
MOTION FOR CONTINUANCE OF COMMON ISSUE  
FACT DISCOVERY ON PROXIMATE CAUSATION**

The Saint Thomas Entities<sup>1</sup> file this motion to amend MDL Order # 9 and the deadlines set forth in Judge Zobel's July 9, 2015 Order<sup>2</sup> to (1) extend the deadline for common issue fact discovery on proximate causation until thirty days (30) after the completion of certain depositions and discovery commenced before September 15, 2014, and (2) extend deadlines related to expert reports until sixty 60 days after completion of such discovery.

## STATUS OF DISCOVERY

This litigation stems from an outbreak of fungal meningitis due to the contamination of pharmaceutical products compounded by New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center. (“NECC”). Plaintiffs have made claims against numerous parties other than NECC, including the Saint Thomas Entities and Saint Thomas Outpatient Neurosurgical Center (“STOPNC”).<sup>3</sup> STOPNC, like thousands of health care providers across

<sup>1</sup> Saint Thomas West Hospital f/k/a St. Thomas Hospital; Saint Thomas Health; and Saint Thomas Network.

<sup>2</sup> See Dkt. No. 2075.

<sup>3</sup> See *Mem. of Decision [re: Motions to Dismiss]* at p. 3 (Dkt. No. 1360).

the country, did nothing more than purchase medication from NECC to administer to patients. The Saint Thomas Entities have been sued because one of them (Saint Thomas Network) owns half of STOPNC. It is uncontested that neither the Saint Thomas Entities nor STOPNC had *any role whatsoever* in causing the contamination. Nor is there any evidence that the Saint Thomas Entities or STOPNC had any knowledge of any contamination by NECC. It is the Saint Thomas Entities' position that those responsible for the contamination itself are the only parties liable for the injuries caused by this unprecedented outbreak. As such, the Saint Thomas Entities have been conducting discovery to determine the persons and entities who caused the contamination—as well as how the contamination occurred—all of which is critical to their defense.

From the beginning, through a mediation process, the Plaintiffs' Steering Committee ("PSC") attempted to shield facts of how the contamination occurred and the various parties who caused it from the Saint Thomas Entities. Documents produced by the mediating parties have slowly come to light, with documents from some parties having been finally produced for the first time as late as September 10, 2015, just five days before the end of the current discovery deadline.

The Saint Thomas Entities have faced significant opposition to their discovery on proximate cause. For example, they served a deposition notice and subpoena on Dr. Philip J. Austin—the cleanroom expert hired by the PSC to inspect the NECC facility shortly after it shut down. In his sworn declaration, Dr. Austin concluded that Liberty Industries, Inc. ("Liberty") proximately caused the fungal contamination by failing to adequately design and construct the cleanroom in which the MPA at issue was compounded.<sup>4</sup> Having settled with Liberty and no longer interested in providing juries with evidence of Liberty's fault, the PSC filed a motion to

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<sup>4</sup> See *Declaration of Dr. Philip J. Austin* (hereinafter "Austin Dec.") at ¶¶ 5 and 54 [Dkt. No. 1651-1]. Note that the initial Declaration of Dr. Philip J. Austin is located at Dkt. 1610-1, and an amended declaration was filed on January 15, 2015 [Dkt. No. 1651].

quash the Saint Thomas Entities' Subpoena, Deposition Notice, and Document Requests.<sup>5</sup> This Court denied the motion to quash.<sup>6</sup>

Dr. Austin's deposition was taken on September 11, 2015, just four days before the current discovery deadline. The deposition highlights the need to extend the deadline for common issue fact discovery on proximate causation. The Saint Thomas Entities will file excerpts from that deposition once the transcript is available, which will demonstrate to the Court the importance of the proximate cause issue and how the PSC agrees additional discovery on that matter is needed. That required discovery includes testimony from NECC employees such as pharmacy technicians, who know the procedures that were used to compound the MPA in question.

Common issue discovery on proximate causation has also been slowed by a host of parties and non-parties invoking the Fifth Amendment. The parties who are undeniably at fault for the contamination, such as Glenn Chin, who compounded the lot of methylprednisolone acetate ("MPA") at issue, and Barry Cadden, who was aware of fungal blooms at NECC yet permitted the continued production and distribution of MPA, are refusing to be deposed.<sup>7</sup> Douglas Conigliaro, a founder of NECC and owner and director of Medical Sales Management, Inc. ("MSM"), the company responsible for marketing and advertising NECC's products, and Carla Conigliaro, a majority shareholder of NECC, both pled the Fifth in response to discovery

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<sup>5</sup> See PSC's Motion to Quash the Saint Thomas Entities' Subpoena, Deposition Notice, and Document Requests to Dr. Philip J. Austin, PhD (Dkt. No. 2069).

<sup>6</sup> See Judge Boal's Order Denying *Motion to Quash Saint Thomas Entities' Subpoena, Deposition Notice, and Document Request to Dr. Philip J. Austin, PhD* (Dkt. No. 2147).

<sup>7</sup> See Motion for Protective Order and Motion to Quash Deposition Notices to the Invoking Defendants (Dkt. No. 1823).

requests.<sup>8</sup> NECC itself, acting by and through a bankruptcy trustee, has likewise refused—on the basis that individuals like Barry Cadden have the discoverable information.<sup>9</sup> And NECC’s affiliates (like Ameridose) have claimed they have nobody to designate as corporate representatives and accordingly are entitled to protection from discovery.<sup>10</sup>

The depositions of several former MSM and NECC employees are currently scheduled for late September. However, these depositions (and as-yet-unscheduled depositions involving the Massachusetts Board of Registration in Pharmacy) are directly impacted by the United States’ Motion for Leave to Intervene and for a Stay of Certain Depositions, filed on September 4, 2015.<sup>11</sup> The hearing on the United States’ motion is set for October 14, 2015—after many of these depositions are set to occur.<sup>12</sup> Accordingly, the Saint Thomas Entities will join in the motion filed by the Tennessee Clinic Defendants regarding those pending matters.

The Saint Thomas Entities’ are entitled at trial to defend themselves by showing that other parties and non-parties proximately caused the contamination that led to injuries and deaths. Indeed, they intend to show that other parties are the sole proximate cause of plaintiffs’ injuries. As this Court is aware, the FDA has refused to produce a representative for deposition, necessitating a motion to compel by the Tennessee Clinic Defendants.<sup>13</sup> That deposition has

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<sup>8</sup> See, e.g., Douglas and Carla Conigliaro’s Objections and Responses to Saint Thomas Entities’ (Second Set of) Requests for Production of Documents.

<sup>9</sup> See Motion of the Chapter 11 Trustee for a Protective Order Pursuant to Fed. R. Civ. P. 26(c) and 45(c) Precluding the Tennessee Clinic Defendants from Conducting a Deposition of New England Compounding Pharmacy, Inc. Pursuant to Fed. R. Civ. P. 30(b)(6) and Quashing Related Deposition Subpoena (Dkt. Nos. 1810-11).

<sup>10</sup> See Motion for Joinder in the Motion for Protective Order filed by Certain Individual Defendants by Ameridose LLC (Dkt. No. 1824); Motion for Joinder in the Motion for Protective Order filed by Certain Individual Defendants and Motion for Protective Order by GDC Properties Management, LLC (Dkt. No. 1826).

<sup>11</sup> See Dkt. No. 2209.

<sup>12</sup> See Dkt. No. 2237.

<sup>13</sup> See Dkt No. 1775. The “Tennessee Clinic Defendants” consist of STOPNC, Howell Allen Clinic, John Culclasure, M.D., Debra Schamberg, Vaughan A. Allen, M.D., Donald Jones, Kenneth Lister, Kenneth Lister, M.D., P.C., and Specialty Surgery Center, PLLC. See also *Motion to Compel the PSC to Respond to Discovery Served by the Tennessee Clinic Defendants* (Dkt. No. 1830).

been allowed, but not until after the criminal trial takes place. The Saint Thomas Entities were also forced into several disputes and filings relating to Ameridose, which continues to refuse to participate in the discovery process. A second motion to compel Ameridose to produce documents is in progress.<sup>14</sup> The Saint Thomas Entities expect that production to yield additional information relating to proximate causation of plaintiffs' injuries. And NECC still has not produced all of the relevant documents in its possession, necessitating another round of briefing.<sup>15</sup>

Despite their reasonable diligence in pursuing discovery on proximate causation, the Saint Thomas Entities will simply not be able to complete such common issue fact discovery by September 15, 2015, the deadline set by the Court in Judge Zobel's Order on July 9, 2015.

In stark contrast to what they have faced in trying to obtain discovery, the Saint Thomas Entities have responded to numerous written discovery requests, produced over 36,000 pages of documents and presented ten witnesses for deposition. The Saint Thomas Entities have also issued discovery requests or subpoenas to NECC, Ameridose, the Insider Defendants, UniFirst, ARL, Victory and Liberty. Despite their diligence, a small amount of discovery relating to proximate cause remains. And such discovery is critical to the Saint Thomas Entities' defenses.

The following is a summary of outstanding discovery matters:

<b>Party/Witness</b>	<b>Written Discovery Served</b>	<b>Written Discovery Status</b>	<b>Deposition Status</b>
Ameridose	RFA, ROGs, RFPs <sup>16</sup>	Dispute pending, first motion to compel denied without	Motion for protective order granted; Rule

<sup>14</sup> Saint Thomas Entities' Cross-Motion to Compel Ameridose to Produce Documents and Corporate Witness (Dkt. No. 1945); Motion to Compel Ameridose LLC to Produce Documents (Dkt. Nos. 2188-89).

<sup>15</sup> Motion to Compel Compliance with Subpoena to NECC (Dkt. No. 2190).

<sup>16</sup> RFA means Requests for Admission, ROGs means Interrogatories, and RFPs means Requests for Production.

		prejudice to a second motion to compel; second motion to compel pending and to be heard before Judge Boal on October 14, 2015	30(b)(6) deposition precluded.
Barry Cadden (NECC owner, manager and head pharmacist)	RFA, ROGs, two sets of RFPs	Refused to answer based primarily on invocation of 5th Amendment; motion to compel entire criminal discovery denied; request for limited discovery sent 9/14/15.	Motion for protective order granted pending resolution of the criminal charges against him.
Lisa Cadden (NECC owner)	RFA, ROGs, RFPs	Refused to answer based on invocation of 5th Amendment	Motion for protection denied; sealed motion for reconsideration pending and to be heard before Judge Boal on October 14, 2015.
Glenn Chin (NECC pharmacist who compounded contaminated MPA)	RFA, ROGs, two sets of RFPs	Refused to answer based primarily on invocation of 5th Amendment; motion to compel entire criminal discovery denied; request for limited discovery sent 9/14/15.	Motion for protective order granted pending resolution of the criminal charges against him.
Carla Conigliaro (NECC owner)	RFA, ROGs, two sets of RFPs	Refused to answer based primarily on invocation of 5th Amendment; motion to compel entire criminal discovery denied; request for limited discovery sent 9/14/15.	Motion for protective order granted pending resolution of the criminal charges against her
Doug Conigliaro (NECC and MSM owner)	RFA, ROGs, two sets of RFPs	Refused to answer based primarily on invocation of 5th Amendment; motion to compel entire criminal discovery denied; request for limited discovery sent 9/14/15.	Motion for protective order granted pending resolution of the criminal charges against him
Greg Conigliaro (Ameridose owner)	RFA, ROGs, two sets of RFPs	Refused to answer based primarily on invocation of 5th Amendment; motion to compel entire criminal discovery denied; request for limited	Motion for protective order granted pending resolution of the criminal charges against him

		discovery sent 9/14/15.	
Mario Giamei (MSM employee, marketed NECC product to STOPNC)	Subpoena issued	Documents to be brought to deposition.	Subpoena issued; government has moved to stay deposition.
John Notarianni (MSM employee, marketed NECC product to STOPNC)	Subpoena issued	Documents to be brought to deposition.	Subpoena issued; government has moved to stay deposition.
Steven Haynes (NECC employee)	Subpoena issued	Documents to be brought to deposition.	Subpoena issued; government has moved to stay deposition.
Owen Finnegan (NECC employee)	Subpoena issued	Documents to be brought to deposition.	Subpoena issued; motion to quash pending; government has moved to stay deposition.
Joseph Connolly (NECC employee)	Subpoena issued	Documents to be brought to deposition.	Subpoena issued; motion to quash pending; government has moved to stay deposition.
Annette Robinson (NECC employee)	Subpoena issued	Documents to be brought to deposition.	Subpoena issued; government has moved to stay deposition.
Cory Fletcher (NECC employee)	Subpoena issued	Documents to be brought to deposition.	Subpoena issued; government has moved to stay deposition.
Belmira Carvalho (NECC employee)	Subpoena issued	Documents to be brought to deposition.	Subpoena issued; government has moved to stay deposition.
Massachusetts Board of Registration in Pharmacy	Subpoena issued	Documents to be brought to deposition.	Subpoena issued; motion for protection denied; government has moved to stay deposition.

MSM	RFA, ROGs, RFPs	Motion to compel filed 9/14/15.	Motion for protective order granted; Rule 30(b)(6) deposition precluded.
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As an example of the importance of this discovery, the NECC witnesses above (not all of whom will plead the Fifth) have important, discoverable information concerning how the contaminated MPA was compounded. This information includes the equipment and procedures used and the likely point of contamination.

Moreover, the clinic that purchased the drugs from NECC for STOPNC did so after seeing NECC's booth at a trade show and being contacted by a sales agents working for MSM. Similarly, MSM marketed NECC to health care providers across Tennessee, including Saint Thomas Hospital. Accordingly, evidence of MSM's sales materials, training videos and training notebooks is extremely important in showing that MSM's misrepresentations were a proximate cause of plaintiffs' injuries. Training videos are particularly important given the fact the MSM witnesses are expected to plead the Fifth, meaning the videos may be the only way the jury hears directly from MSM as to the sales tactics it employed. This information still has not been produced to the Saint Thomas Entities despite the fact it was requested long ago. It was only recently that the Saint Thomas Entities learned that this specific material existed and had not been produced (through letters from the Government filed in the criminal action).

The remaining discovery is clearly and highly relevant, and the Saint Thomas Entities would be materially prejudiced if they were not able to obtain it. Consequently, they seek a continuance to insure sufficient time and opportunity to properly complete common issue fact discovery on proximate causation and to obtain the expert witnesses they need to prepare their defenses for summary judgment and trial.



The Saint Thomas Entities also seek an extension of deadlines related to expert discovery. Expert reports involving proximate causation cannot be prepared prior to the completion of fact discovery on proximate causation. Thus, the Saint Thomas Entities respectfully request that the Court also postpone the current deadlines for service of expert reports pending completion of such discovery.

### **ARGUMENT AND AUTHORITIES**

A judge has broad discretion to manage scheduling and discovery. *See United States v. 29,540.00 in United States Currency*, 2013 U.S. Dist. LEXIS 9735, \*15 (D. Mass. Jan. 24, 2013). A scheduling order may be modified for good cause and with the judge's consent. *See Fed. R. Civ. P. 16(b)(4); Girl Scouts of the USA, et al.*, 383 F.3d 7, 12 (1<sup>st</sup> Cir. 2014). Good cause exists where a deadline "may not reasonably be met, despite the diligence of the party seeking the extension." *See House of Clean, Inc. v. St. Paul Fire & Marine Ins. Co.*, 775 F. Supp. 2d 296, 298 (D. Mass. 2011) (citing *Tele-Connections, Inc. v. Perception Tech. Corp.*, Civ. A. No. 88-2365-S, 1990 WL 180707, at \*1 (D. Mass. Nov. 5, 1990)). As the information above and attached declaration demonstrate, the Saint Thomas Entities have diligently pursued written and oral discovery against numerous parties and nonparties. *See Declaration of Adam T. Schramek*, attached as Exhibit A.

As previously discussed, the Saint Thomas Entities have alternatively asserted in their answers that any liability they may have should be reduced because other parties and nonparties—including the specific persons and/or entities from which they are seeking discovery—proximately caused the contamination at issue.<sup>17</sup> The relevance and necessity of the discovery at issue includes, without limitation, the following:

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<sup>17</sup> *See Saint Thomas Entities' Master Answer to Complaint* (Dkt. No. 1464).

- The work flow and procedures for compounding the MPA at issue, including identification of the point of contamination. While Dr. Austin has concluded that the contamination occurred from debris above the ceiling that fell between gaps in the ceiling grid, he was unable at his deposition last week to identify the point in the compounding process where the contamination occurred.
- The oversight, management and operation of NECC by its owners, directors, and managers. This evidence is needed so the jury may properly conclude that the criminal defendants' actions proximately caused plaintiffs' injuries and that such criminal actions broke the causal chain as to the Saint Thomas Entities.
- The representations and marketing strategies of MSM, which falsely stated that the NECC facility and its products were compliant with all required industry standards. Evidence from MSM and its sales force is needed so that the jury may conclude that MSM's misrepresentations proximately caused plaintiffs' injuries.
- The regulatory history of NECC and Ameridose by state and federal regulators. Evidence from the FDA and the Massachusetts Board of Registration in Pharmacy is needed so that the jury may properly conclude that the failure of regulators to ensure that NECC compounded medication free from contamination and in compliance with applicable state and federal law proximately caused plaintiffs' injuries.

Not only is the remaining discovery essential to the Saint Thomas Entities' defenses, but neither the PSC nor any other party will be prejudiced by a continuance and extension of deadlines related to expert discovery. The Saint Thomas Entities simply seek an extension of the

deadlines for common issue fact discovery on proximate causation so that they may obtain the discovery already requested and address any additional matters that may arise from such discovery. There are no trial dates currently set.

In conclusion, despite their reasonable diligence, the Saint Thomas Entities need additional time to develop evidence that is not only relevant, but essential to their defenses in these proceedings. The continuance is not sought for the purposes of delay, but so that the Saint Thomas Entities will be able to defend themselves and justice may be done. Accordingly, they ask the Court to continue the common fact issue discovery deadline. The extension on common issue fact discovery will likewise necessitate an extension on deadlines related to expert reports and discovery.<sup>18</sup> Pursuant to Local Rule 40.3(b), the Saint Thomas Entities sought a continuance of the common issue fact discovery on May 13, 2015.<sup>19</sup> The motion was granted in part on July 9, 2015, extending common fact discovery to September 15, 2015.<sup>20</sup> As discussed above, a significant amount of discovery has occurred since then.

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<sup>18</sup> Pursuant to Judge Zobel's July 9, 2015 Order, Opening Common Expert Reports are currently due October 16, 2015; Rebuttal Common Expert Reports are currently due November 13, 2015; Reply Common Expert Reports are currently due November 24, 2015; and Common Expert Discovery closes on December 11, 2015.

<sup>19</sup> See Dkt. Nos. 1849-51.

<sup>20</sup> See Dkt. No. 2075.

Dated: Sept. 14, 2015

SAINT THOMAS WEST HOSPITAL F/K/A ST.  
THOMAS HOSPITAL, SAINT THOMAS  
HEALTH, AND SAINT THOMAS NETWORK

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**CERTIFICATE OF SERVICE**

I certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing this 14<sup>th</sup> day of September, 2015.

/s/ Sarah P. Kelly

Sarah P. Kelly

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